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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/025,222 | 12/19/2001 | Jerry Pelletier | 073406-0701 | 4998 |

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| EXAMINER | |
|---|---|
| STEADMAN, DAVID J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1656 | |

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/025,222 | PELLETIER ET AL. | |
| | Examiner | Art Unit | |
| | David J. Steadman | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *66,72,88,91,105,106 and 109-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *66,88,105,106,109,110,117 and 118* is/are allowed.

6)☒ Claim(s) *72 and 91* is/are rejected.

7)☒ Claim(s) *111-116,119 and 120* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *APPENDIX A*.

## DETAILED ACTION

### *Status of the Application*

**[1]** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2005 has been entered.

**[2]** Claims 66, 72, 88, 91, 105-106, and 109-120 are pending in the application.

**[3]** Applicant's amendment to the claims, filed on 12/27/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

**[4]** Receipt of a Statement of Substance of Interview, filed on 1/17/2005, is acknowledged. Said Statement corresponds to the telephonic interview conducted on 12/20/2005. See Interview Summary filed on 12/29/2005.

**[5]** Applicant's arguments filed on 12/27/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

**[6]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

### *Claim Objections*

**[7]** Claims 111 and 112 are objected to as not reciting "and" between method steps (a) and (b). Appropriate correction is required.

***Claim Rejections – 35 USC § 112, Second Paragraph***

**[8]** Claim 91 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the recitation of "said isolated or purified polypeptide" at the end of claim 91, it would appear that the phrase "wherein said isolated or purified polypeptide has RNA primase activity" would apply to parts (a) and (b) of claim 91. However, because the phrase "wherein said isolated or purified polypeptide has RNA primase activity" appears to be part of claim 91 part (b), it is unclear as to whether the recitation of "wherein said isolated or purified polypeptide has RNA primase activity" is meant to apply only to an isolated or purified polypeptide comprising the second amino acid sequence or whether this limitation is meant to apply to an isolated or purified polypeptide comprising either the first or the second amino acid sequence. It is suggested that applicant clarify the meaning of the claim. In the interest of advancing prosecution, the examiner has interpreted claim 91 as meaning that the limitation "wherein said isolated or purified polypeptide has RNA primase activity" applies equally to a polypeptide comprising either the first or the second amino acid sequence.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use
> or on sale in this country, more than one year prior to the date of application for patent in the United States.

**[9]** Claim(s) 72 is rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al. (WO 99/37661; cited in the IDS filed July 07, 2003 as reference A7). Claim 72 is drawn to a polypeptide comprising SEQ ID NO:6 at the C-terminal end thereof, which binds to SEQ ID NO:4.

O'Donnell et al. teaches a polypeptide (see Appendix A) that has a C-terminal sequence (see amino acids 534 to 572 of the polypeptide of O'Donnell et al.) that is 100% identical to SEQ ID NO:6. This anticipates claim 72 as written.

It is noted that O'Donnell et al. fails to teach that their disclosed polypeptide binds to SEQ ID NO:4. However, according to the specification, the presence of SEQ ID NO:6 at the C-terminal end of a polypeptide imparts the ability of that polypeptide to bind SEQ ID NO:4 (see particularly Figure 10 and pp. 14-16 of the response filed on 9/1/2004). Because the polypeptide of O'Donnell et al. has the sequence of SEQ ID NO:6 at the C-terminal end, it follows that it would have the ability to bind SEQ ID NO:4. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the

protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

***Conclusion***

**[10]** Status of the claims:

Claims 66, 72, 88, 91, 105-106, and 109-120 are pending.

Claims 66, 88, 105-106, 109-110, 117, and 118 appear to be in a condition for allowance.

Claims 72 and 91 are rejected.

Claims 111 and 112 are objected to and claims 113-116 and 119-120 are objected to as being dependent therefrom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656

## APPENDIX A

```
AAY49072
ID   AAY49072 standard; Protein; 572 AA.
XX
AC   AAY49072;
XX
DT   05-JAN-2000  (first entry)
XX
DE   Amino acid sequence encoded by partial dnaG gene.
XX
KW   Gram positive bacteria; dnaE; dnaX; dnaB; PolC; dnaN; dnaG; helicase;
KW   alpha subunit; DNA polymerase III holoenzyme; gamma subunit; tau subunit;
KW   primase; clamp loader; glue protein; replication; antibiotic.
XX
OS   Staphylococcus aureus.
XX
PN   WO9937661-A1.
XX
PD   29-JUL-1999.
XX
PF   25-JAN-1999;   99WO-US01547.
XX
PR   27-JAN-1998;   98US-0074522.
PR   22-JUL-1998;   98US-0093727.
XX
PA   (UYRQ ) UNIV ROCKEFELLER.
XX
PI   O'Donnell ME,  Zhang D,  Whipple R;
XX
DR   WPI; 1999-590685/50.
DR   N-PSDB; AAZ31006.
XX
PT   New isolated dnaE, dnaX and dnaB genes from Gram positive bacteria,
PT   used to develop screening assays for identifying antibiotic compounds
PT   -
XX
PS   Disclosure; Page 33-34; 132pp; English.
XX
CC   This is the amino acid sequence encoded by the Staphylococcus aureus
CC   partial dnaG gene. The invention relates to a number of isolated DNA
CC   molecules from Gram positive bacterium, corresponding to dnaE
CC   (AAZ31001), dnaX (AAZ31002),and dnaB (AAZ31003). The PolC, dnaN and dnaG
CC   genes (AAZ31004-Z31006) are also identified. The dnaE gene corresponds to
CC   the alpha subunit of the Escherichia coli, DNA polymerase III
CC   holoenzyme, dnaX corresponds to the gamma and tau subunits, and dnaB
CC   corresponds to the helicase. The alpha subunit is the actual DNA
CC   polymerase, the gamma complex forms the clamp loader and tau is a "glue
CC   protein". DnaX encodes both gamma and Tau, Tau is the product of the full
CC   gene, while gamma is the product of the first two thirds of the gene.
CC   DnaN forms the beta subunit which forms the sliding clamp, and dnaG
CC   encodes a primase. The DNA sequences of the invention can be used to
CC   identify agents that inhibit or promote DNA replication by acting on
CC   various parts of the gram positive bacterial DNA polymerase holoenzyme.
CC   The products and methods of the invention can be used for identifying
CC   pharmacological agents or lead compounds for agents active at the level
CC   of a replication protein function, particularly DNA replication. The
CC   agents identified can be used as antibiotics.
XX
SQ   Sequence   572 AA;

  Query Match             93.5%;  Score 2906;  DB 20;  Length 572;
  Best Local Similarity   98.1%;  Pred. No. 6.4e-220;
  Matches  560;  Conservative    3;  Mismatches    2;  Indels    6;  Gaps    1;

Qy         35 IGLCPFHDEKTPSFTVSEDKQICHCFGCKKGGNVFQFTQEIKDISFVEAVKELGDRVNVA 94
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          2 IGLCPFHDEKTPSFTVSEDKQICHCFGCKKGGNVFQFTQEIKDISFVEAVKELGDRVNVA 61
```

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Qy        95 VDIEATQSNSNVQIASDDLQMIEMHELIQEFYYYALTKTVEGEQALTYLQERGFTDALIK 154
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        62 VDIEATQSNSNVQIASDDLQMIEMHELIQEFYYYALTKTVEGEQALTYLQERGFTDALIK 121

Qy       155 ERGIGFAPDSSHFCHDFLQKKGYDIELAYEAGLLSRNEENFSYYDRFRNRIMFPLKNAQG 214
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       122 ERGIGFAPDSSHFCHDFLQKKGYDIELAYEAGLLSRNEENFSYYDRFRNRIMFPLKNAQG 181

Qy       215 RIVGYSGRTYTGQEPKYLNSPETPIFQKRKLLYNLDKARKSIRKLDEIVLLEGFMDVIKS 274
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       182 RIVGYSGRTYTGQEPKYLNSPETPIFQKRKLLYNLDKARKSIRKLDEIVLLEGFMDVIKS 241

Qy       275 DTAGLKNVVATMGTQLSDEHITFIRKLTSNITLMFDGDFAGSEATLKTGQNLLQQGLNVF 334
             ||||||||||||||||||||||||||||||||||||||||||||||||||:|||||||||
Db       242 DTAGLKNVVATMGTQLSDEHITFIRKLTSNITLMFDGDFAGSEATLKTGQHLLQQGLNVF 301

Qy       335 VIQLPSGMDPDEYIGKYGNDAFTAFVKNDKKSFAHYKVSILKDEIAHNDLSYERYLKELS 394
             |||||||||||||||||||||| ||||||||||||||||||||||||||||||||||||||
Db       302 VIQLPSGMDPDEYIGKYGNDAFTTFVKNDKKSFAHYKVSILKDEIAHNDLSYERYLKELS 361

Qy       395 HDISLMKSSILQQKALNDVAPFFNVSPEQLANEIQFNQAPANYYPE------DEYGGYIE 448
             ||||||||||||||:|||||||||||||||||||||||||||||||      ||||||||
Db       362 HDISLMKSSILQQKAINDVAPFFNVSPEQLANEIQFNQAPANYYPEDEYGGYDEYGGYIE 421

Qy       449 PEPIGMAQFDNLSRQEKAERAFLKHLMRDKDTFLNYYESVDKDNFTNQHFKYVFEVLHDF 508
             ||||||||||||||:|||||||||||||||||||||||||||||||||||||||||||||
Db       422 PEPIGMAQFDNLSRREKAERAFLKHLMRDKDTFLNYYESVDKDNFTNQHFKYVFEVLHDF 481

Qy       509 YAENDQYNISDAVQYVNSNELRETLISLEQYNLNDEPYENEIDDYVNVINEKGQETIESL 568
             |||||||||||||||||||||||||||||||| ||||||||||||||||||||||||||||
Db       482 YAENDQYNISDAVQYVNSNELRETLISLEQYNLNGEPYENEIDDYVNVINEKGQETIESL 541

Qy       569 NHKLREATRIGDVELQKYYLQQIVAKNKERM 599
             |||||||||||||||||||||||||||||||
Db       542 NHKLREATRIGDVELQKYYLQQIVAKNKERM 572
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